

# HOUSE BILL 512

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By: **Delegates Barron, Bagnall, Buckel, Kipke, R. Lewis, and Szeliga**

Introduced and read first time: January 27, 2020

Assigned to: Health and Government Operations

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Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 4, 2020

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## CHAPTER \_\_\_\_\_

1 AN ACT concerning

2 **Drugs and Devices – Electronic Prescriptions – Controlled Dangerous**  
3 **Substances**

4 FOR the purpose of authorizing certain controlled dangerous substance prescriptions to be  
5 dispensed on an electronic prescription; requiring, except under certain  
6 circumstances, a certain health practitioner to issue a prescription for a controlled  
7 dangerous substance electronically; authorizing an authorized prescriber to issue a  
8 written or oral prescription for a controlled dangerous substance only under certain  
9 circumstances; requiring the Secretary of Health, in collaboration with the Maryland  
10 Health Care Commission, to adopt certain regulations regarding a certain waiver  
11 that includes certain provisions; authorizing the Secretary to issue a waiver that  
12 applies generally to a certain group of health practitioners or drugs; providing that  
13 a certain waiver shall apply to a certain health practitioner without requiring the  
14 health practitioner to go through a certain process; authorizing the Secretary to  
15 adopt certain regulations regarding certain exceptions to the requirement to issue  
16 an electronic prescription; authorizing a certain health occupations board to take  
17 certain action against a health practitioner who violates certain provisions of this  
18 Act; authorizing a pharmacist to dispense a drug on a prescription transmitted in a  
19 certain manner under certain circumstances; providing that a pharmacist who  
20 receives certain prescriptions is not required to verify certain information about the  
21 prescription; altering the circumstances under which a pharmacist may refill and  
22 dispense a prescription; making conforming changes; providing for the construction  
23 of certain provisions of this Act; defining a certain term; providing for a delayed  
24 effective date; and generally relating to electronic prescriptions for controlled  
25 dangerous substances.

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 BY repealing and reenacting, without amendments,  
2 Article – Correctional Services  
3 Section 1–101(a), (d), (n), and (o)  
4 Annotated Code of Maryland  
5 (2017 Replacement Volume and 2019 Supplement)

6 BY repealing and reenacting, without amendments,  
7 Article – Criminal Law  
8 Section 5–101(a)  
9 Annotated Code of Maryland  
10 (2012 Replacement Volume and 2019 Supplement)

11 BY adding to  
12 Article – Criminal Law  
13 Section 5–101(p–1)  
14 Annotated Code of Maryland  
15 (2012 Replacement Volume and 2019 Supplement)

16 BY repealing and reenacting, with amendments,  
17 Article – Criminal Law  
18 Section 5–501, 5–504, and 5–701  
19 Annotated Code of Maryland  
20 (2012 Replacement Volume and 2019 Supplement)

21 BY repealing and reenacting, with amendments,  
22 Article – Health – General  
23 Section 21–220  
24 Annotated Code of Maryland  
25 (2019 Replacement Volume)

26 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,  
27 That the Laws of Maryland read as follows:

28 **Article – Correctional Services**

29 1–101.

30 (a) In this article the following words have the meanings indicated.

31 (d) “Correctional facility” means a facility that is operated for the purpose of  
32 detaining or confining adults who are charged with or found guilty of a crime.

33 (n) “State” means:

34 (1) a state, possession, territory, or commonwealth of the United States; or



1 (ii) dispenses the controlled dangerous substance directly to an  
2 ultimate user; or

3 (2) a pharmacist if:

4 (i) an emergency exists;

5 (ii) the pharmacist dispenses the drug under regulations of the  
6 Department on an oral prescription that the pharmacist reduces promptly to writing and  
7 keeps on file; and

8 (iii) federal law authorizes the oral prescription.

9 (c) A prescription for a controlled dangerous substance listed in Schedule II shall  
10 be kept on file in conformity with the requirements for records and inventories under §  
11 5–306 of this title.

12 (d) A person may not refill a prescription for a controlled dangerous substance  
13 listed in Schedule II.

14 5–504.

15 (a) Except when dispensed directly to an ultimate user by an authorized provider  
16 who is not a pharmacist, a controlled dangerous substance listed in Schedule III or  
17 Schedule IV that is a drug to which § 21–220 of the Health – General Article applies may  
18 not be dispensed without a written **PRESCRIPTION, AN ELECTRONIC PRESCRIPTION, or**  
19 **AN** oral prescription.

20 (b) Unless renewed by the authorized provider, the prescription may not be:

21 (1) filled or refilled more than 6 months after the date of prescription; or

22 (2) refilled more than five times.

23 5–701.

24 (a) Sections 5–701 through 5–704 of this subtitle apply to:

25 (1) the sale of prescription drugs by a manufacturer, wholesale distributor,  
26 retail pharmacist, or jobber to a person not legally qualified or authorized to purchase and  
27 hold prescription drugs for use or resale; and

28 (2) an authorized provider's assistant who is not licensed to administer  
29 prescription drugs.

30 (b) A person may not dispense a prescription drug except:

1 (1) on an authorized provider's:

2 (I) **ELECTRONIC PRESCRIPTION;**

3 [(i)] (II) written prescription; or

4 [(ii)] (III) oral prescription that the pharmacist reduces to writing  
5 and files; or

6 (2) by refilling a written **PRESCRIPTION, AN ELECTRONIC**  
7 **PRESCRIPTION,** or AN oral prescription that is authorized:

8 (i) by the authorized provider in the original prescription; or

9 (ii) by oral direction that the pharmacist reduces to writing and files.

10 (c) A person may not dispense a prescription drug by filling or refilling a written  
11 **PRESCRIPTION, AN ELECTRONIC PRESCRIPTION,** or AN oral prescription of an  
12 authorized provider unless the drug bears a label that, in addition to any requirements of  
13 the Department or federal law, contains:

14 (1) the name and address of the dispenser;

15 (2) the serial number and date of the prescription;

16 (3) the name of the authorized provider; and

17 (4) if stated in the prescription, the name and address of the patient and  
18 the directions for use.

19 (d) Except as otherwise provided under this title, a person may not:

20 (1) manufacture, distribute, or possess with intent to distribute a  
21 prescription drug;

22 (2) affix a false or counterfeit label to a package, container, or other  
23 receptacle containing a prescription drug;

24 (3) omit, remove, alter, or obliterate a label or symbol that is required by  
25 federal, State, or local law on a prescription drug; or

26 (4) obtain or attempt to obtain a prescription drug by:

27 (i) fraud, deceit, or misrepresentation;

- 1 (ii) the counterfeiting or altering of a prescription or written order;
- 2 (iii) concealing a material fact;
- 3 (iv) using a false name or address;
- 4 (v) falsely assuming the title of or falsely representing that the  
5 person is a manufacturer, distributor, or authorized provider; or
- 6 (vi) making or issuing a false or counterfeit prescription or written  
7 order.

8 (e) A person who violates this section is guilty of a misdemeanor and on conviction  
9 is subject to imprisonment not exceeding 2 years or a fine not exceeding \$1,000 or both.

### 10 Article – Health – General

11 21–220.

12 (a) A drug that is intended for use by human beings and is in any of the following  
13 classifications may be dispensed by a pharmacist only on a written **PRESCRIPTION, AN**  
14 **ELECTRONIC PRESCRIPTION, AS DEFINED IN § 5–101 OF THE CRIMINAL LAW**  
15 **ARTICLE**, or AN oral prescription from a health practitioner authorized by law to prescribe  
16 the drug:

17 (1) A habit–forming drug to which § 21–218(b)(1) of this subtitle applies.

18 (2) A drug that because of its toxicity or other potentiality for harmful  
19 effect, the method of its use, or the collateral measures necessary to its use, is not safe for  
20 use except under the supervision of a health practitioner who is authorized by law to  
21 administer such a drug.

22 (3) A drug that is limited by an approved application under § 355 of the  
23 federal act or § 21–223 of this subtitle to use under the professional supervision of a health  
24 practitioner authorized by law to administer such a drug.

25 (b) (1) **[A] SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION AND**  
26 **SUBSECTION (C) OF THIS SECTION, A prescription may be written or oral OR MADE**  
27 **THROUGH AN ELECTRONIC PRESCRIPTION.**

28 (2) **[However, a] A pharmacist may not dispense a drug on an oral**  
29 **prescription unless the pharmacist promptly writes out and files the prescription.**

30 (c) (1) **EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, A**  
31 **HEALTH PRACTITIONER AUTHORIZED BY LAW TO PRESCRIBE A CONTROLLED**  
32 **DANGEROUS SUBSTANCE WITHIN THE MEANING OF TITLE 5 OF THE CRIMINAL LAW**

1 ARTICLE SHALL ISSUE A PRESCRIPTION FOR A CONTROLLED DANGEROUS  
2 SUBSTANCE USING AN ELECTRONIC PRESCRIPTION, AS DEFINED IN § 5-101 OF THE  
3 CRIMINAL LAW ARTICLE.

4 (2) A HEALTH PRACTITIONER MAY ISSUE A WRITTEN OR, IF  
5 AUTHORIZED BY STATE AND FEDERAL LAW, ORAL PRESCRIPTION FOR A  
6 CONTROLLED DANGEROUS SUBSTANCE ONLY IF:

7 (I) ELECTRONIC PRESCRIBING IS NOT AVAILABLE DUE TO  
8 TEMPORARY TECHNOLOGICAL OR ELECTRICAL FAILURE;

9 (II) THE PRESCRIPTION IS TO BE DISPENSED BY A PHARMACY  
10 LOCATED OUTSIDE THE STATE;

11 ~~(III) THE PRESCRIBING ENTITY AND DISPENSING ENTITY OF THE~~  
12 ~~DRUG OR DEVICE ARE THE SAME;~~

13 (III) THE PRESCRIPTION IS ISSUED BY A HEALTH PRACTITIONER  
14 OUTSIDE THE STATE;

15 (IV) THE HEALTH PRACTITIONER IS PRESCRIBING AND  
16 DISPENSING THE CONTROLLED DANGEROUS SUBSTANCE DIRECTLY TO THE  
17 PATIENT;

18 (V) THE PRESCRIPTION IS BEING DISPENSED DIRECTLY TO THE  
19 PATIENT IN ACCORDANCE WITH § 12-102(C)(2)(IV) OF THE HEALTH OCCUPATIONS  
20 ARTICLE;

21 ~~(IV)~~ (VI) THE PRESCRIPTION IS FOR AN INDIVIDUAL WHO:

22 1. RESIDES IN A NURSING OR ASSISTED LIVING  
23 FACILITY;

24 2. IS RECEIVING CARE THROUGH A HOSPICE OR  
25 PALLIATIVE CARE PROGRAM AND THE PRESCRIPTION IS RELATED TO THE CARE  
26 PROVIDED; ~~OR~~

27 3. IS RECEIVING CARE AT AN OUTPATIENT RENAL  
28 DIALYSIS FACILITY AND THE PRESCRIPTION IS RELATED TO THE CARE PROVIDED;  
29 OR

30 4. IS INCARCERATED IN A STATE CORRECTIONAL  
31 FACILITY, AS DEFINED IN § 1-101 OF THE CORRECTIONAL SERVICES ARTICLE;

1                   ~~(v)~~ (VII) THE PRESCRIPTION IS ISSUED BY A LICENSED  
2 VETERINARIAN;

3                   ~~(vi)~~ (VIII) THE PRESCRIPTION INCLUDES ELEMENTS THAT ARE  
4 NOT SUPPORTED BY THE MOST RECENT VERSION OF THE NATIONAL COUNCIL FOR  
5 PRESCRIPTION DRUG PROGRAMS PRESCRIBER/PHARMACIST INTERFACE SCRIPT  
6 STANDARD;

7                   ~~(vii)~~ (IX) THE PRESCRIPTION IS ISSUED FOR A DRUG FOR  
8 WHICH THE FEDERAL FOOD AND DRUG ADMINISTRATION REQUIRES THE  
9 PRESCRIPTION TO CONTAIN CERTAIN ELEMENTS THAT CANNOT BE TRANSMITTED  
10 ELECTRONICALLY;

11                   ~~(viii) THE PRESCRIPTION IS NOT SPECIFIC TO ONE PATIENT,  
12 INCLUDING PRESCRIPTIONS THAT ARE:~~

13                   ~~1. IN ACCORDANCE WITH A STANDING ORDER;~~

14                   ~~2. FOR AN APPROVED PROTOCOL FOR DRUG THERAPY;~~

15                   ~~3. FOR COLLABORATIVE DRUG MANAGEMENT;~~

16                   ~~4. FOR COMPREHENSIVE MEDICATION MANAGEMENT;~~

17 ~~OR~~

18                   ~~5. IN RESPONSE TO A PUBLIC HEALTH EMERGENCY;~~

19                   ~~(ix)~~ (X) THE PRESCRIPTION PRESCRIBES A DRUG UNDER A  
20 RESEARCH PROTOCOL;

21                   ~~(x)~~ (XI) THE PRESCRIPTION IS ISSUED BY A HEALTH  
22 PRACTITIONER WHO HAS RECEIVED A WAIVER UNDER SUBSECTION (D)(1) OF THIS  
23 SECTION;

24                   ~~(xi)~~ (XII) THE PRESCRIPTION IS ISSUED BY A HEALTH  
25 PRACTITIONER WHO REQUESTED A WAIVER UNDER SUBSECTION (D)(1) OF THIS  
26 SECTION AND THE DEPARTMENT HAS NOT ISSUED A WAIVER TO THE PRACTITIONER  
27 OR HAS NOT REJECTED THE PRACTITIONER'S REQUEST FOR A WAIVER;

28                   ~~(xii)~~ (XIII) THE HEALTH PRACTITIONER ISSUING THE  
29 PRESCRIPTION OR THE DRUG FOR WHICH THE PRESCRIPTION IS ISSUED FALLS  
30 UNDER A WAIVER ISSUED BY THE SECRETARY UNDER SUBSECTION (D)(2) OF THIS  
31 SECTION;



1           ~~(XIII)~~ (XIV) THE PRESCRIPTION IS ISSUED BY A HEALTH  
2 PRACTITIONER WHO WRITES A LOW VOLUME OF PRESCRIPTIONS FOR CONTROLLED  
3 DANGEROUS SUBSTANCES, AS DETERMINED BY THE MARYLAND HEALTH CARE  
4 COMMISSION; OR

5           ~~(XIV)~~ (XV) THE PRESCRIPTION IS ISSUED BY A HEALTH  
6 PRACTITIONER UNDER CIRCUMSTANCES IN WHICH, ALTHOUGH THE PRACTITIONER  
7 HAS THE ABILITY TO ISSUE AN ELECTRONIC PRESCRIPTION AS REQUIRED BY  
8 PARAGRAPH (1) OF THIS SUBSECTION, THE HEALTH PRACTITIONER REASONABLY  
9 DETERMINES THAT:

10                   1. IT WOULD BE IMPRACTICABLE FOR THE  
11 PRACTITIONER TO PRESCRIBE THE DRUG OR DEVICE BY ELECTRONIC  
12 PRESCRIPTION IN A TIMELY MANNER; AND

13                   2. THE DELAY WOULD ADVERSELY IMPACT THE  
14 PATIENT'S MEDICAL CONDITION.

15           (3) THIS SUBSECTION MAY NOT BE CONSTRUED TO LIMIT THE RIGHT  
16 OF A PATIENT TO DESIGNATE A SPECIFIC PHARMACY TO DISPENSE A PRESCRIBED  
17 DRUG OR DEVICE TO THE INDIVIDUAL.

18           (D) (1) THE SECRETARY SHALL ADOPT REGULATIONS, IN  
19 COLLABORATION WITH THE MARYLAND HEALTH CARE COMMISSION, TO  
20 ESTABLISH A PROCESS FOR THE DEPARTMENT TO ISSUE A WAIVER FROM THE  
21 ELECTRONIC PRESCRIPTION REQUIREMENTS IN SUBSECTION (C)(1) OF THIS  
22 SECTION.

23                   (2) (I) THE SECRETARY MAY ISSUE A WAIVER THAT APPLIES  
24 GENERALLY TO A GROUP OF HEALTH PRACTITIONERS OR DRUGS THAT MEET  
25 CONDITIONS SPECIFIED BY THE SECRETARY.

26                   (II) ANY WAIVER ISSUED UNDER SUBPARAGRAPH (I) OF THIS  
27 PARAGRAPH FOR A GROUP OF HEALTH PRACTITIONERS SHALL APPLY TO A HEALTH  
28 PRACTITIONER IN THAT GROUP WITHOUT REQUIRING THE HEALTH PRACTITIONER  
29 TO GO THROUGH THE PROCESS ESTABLISHED IN REGULATIONS UNDER PARAGRAPH  
30 (1) OF THIS SUBSECTION.

31           (3) EXCEPT FOR A WAIVER ISSUED UNDER PARAGRAPH (2) OF THIS  
32 SUBSECTION, THE REGULATIONS ADOPTED UNDER PARAGRAPH (1) OF THIS  
33 SUBSECTION SHALL SPECIFY THAT A WAIVER:

34                   (I) MAY NOT EXCEED 1 YEAR; AND

1 (II) MAY BE GRANTED FOR THE FOLLOWING REASONS:

2 1. ECONOMIC HARDSHIP;

3 2. TECHNOLOGICAL LIMITATIONS THAT ARE NOT  
4 REASONABLY WITHIN THE CONTROL OF THE HEALTH PRACTITIONER; OR

5 3. ANY OTHER EXCEPTIONAL CIRCUMSTANCES AS  
6 DEMONSTRATED BY THE HEALTH PRACTITIONER.

7 (4) THE SECRETARY MAY ADOPT REGULATIONS ON:

8 (I) WHICH TEMPORARY TECHNOLOGICAL OR ELECTRICAL  
9 FAILURES CONSTITUTE AN EXCEPTION TO THE REQUIREMENT TO ISSUE AN  
10 ELECTRONIC PRESCRIPTION UNDER SUBSECTION (C)(1) OF THIS SECTION; AND

11 (II) THE CIRCUMSTANCES UNDER WHICH A HEALTH  
12 PRACTITIONER IS EXEMPT FROM THE REQUIREMENT TO ISSUE AN ELECTRONIC  
13 PRESCRIPTION UNDER SUBSECTION (C)(1) OF THIS SECTION BECAUSE THE  
14 PRESCRIPTION WILL BE DISPENSED BY A PHARMACY LOCATED OUTSIDE THE STATE.

15 (E) THE APPROPRIATE HEALTH OCCUPATIONS BOARD ESTABLISHED  
16 UNDER THE HEALTH OCCUPATIONS ARTICLE MAY TAKE DISCIPLINARY ACTION  
17 AGAINST A HEALTH PRACTITIONER WHO VIOLATES SUBSECTION (C) OF THIS  
18 SECTION.

19 (F) (1) A PHARMACIST MAY DISPENSE A DRUG ON A WRITTEN OR ORAL  
20 PRESCRIPTION FOR A CONTROLLED DANGEROUS SUBSTANCE THAT MEETS THE  
21 REQUIREMENTS OF THIS SECTION.

22 (2) A PHARMACIST WHO RECEIVES A WRITTEN OR ORAL  
23 PRESCRIPTION IS NOT REQUIRED TO VERIFY THAT THE PRESCRIPTION IS AN  
24 AUTHORIZED EXCEPTION TO THE ELECTRONIC PRESCRIPTION REQUIREMENT  
25 UNDER SUBSECTION (C)(2) OF THIS SECTION.

26 [(2)] (G) (1) [A] IF A prescription for a controlled dangerous substance  
27 within the meaning of Title 5 of the Criminal Law Article IS WRITTEN, IT may not be  
28 written on a preprinted prescription form that states the name, quantity, or strength of the  
29 controlled dangerous substance.

30 [(3)] (2) When a prescription is written, a separate prescription form is  
31 required for each controlled dangerous substance. If a pharmacist is otherwise satisfied  
32 that a prescription is valid the pharmacist may fill the prescription if the pharmacist  
33 promptly writes out and files a prescription for each substance and also files the original  
34 prescription.

1           **[(4)] (3)**       A WRITTEN prescription shall be legible.

2           **[(c)] (H)**       A pharmacist may not refill and dispense a prescription unless the  
3 refilling is authorized by:

4           (1)       The health practitioner's specification in the original prescription as to  
5 how many times it may be refilled; ~~for~~

6           (2)       An oral order of the health practitioner that promptly is written out and  
7 filed by the pharmacist; ~~OR~~

8           ~~**(3)**       **AN ELECTRONIC ORDER OF THE HEALTH PRACTITIONER.**~~

9           **[(d)] (I)**       The dispensing of a drug without complying with the requirements of  
10 this section is the dispensing of a misbranded drug.

11           **[(e)] (J)**       (1)       A drug that is subject to the prescription requirements of this  
12 section is misbranded if, at any time before it is dispensed, its label does not bear the  
13 statement "Caution: Federal Law Prohibits Dispensing Without Prescription", or "Caution:  
14 State Law Prohibits Dispensing Without Prescription".

15           (2)       A drug to which the prescription requirements of this section do not  
16 apply is misbranded if, at any time before it is dispensed, its label bears the caution  
17 statement quoted in paragraph (1) of this subsection.

18           **[(f)] (K)**       (1)       The prescription requirements of this section do not apply to any  
19 drug that is exempted under a rule or regulation adopted by the Secretary.

20           (2)       The Secretary, by rule or regulation, may exempt any drug from the  
21 requirements of this section if the Secretary finds that, as to the drug, the requirements of  
22 this section are not necessary for the protection of the public health.

23           (3)       The Secretary, by rule and regulation, may exempt from the  
24 requirements of this section any drug that is removed from the prescription requirements  
25 of the federal act by a rule or regulation adopted under that act.

26           SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
27 January 1, ~~2021~~ 2022.